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EXAMINER

KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

124

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/744,852

Applicant(s)

FROHBERG, CLAUS

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-24 and 26-42 is/are pending in the application.
- 4a) Of the above claim(s) 22 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-21,24 and 26-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

The rejection of Claims 1, 3, 5 and 6 under 35 U.S.C. 101 is withdrawn in view of Applicant's amendments. Claims 6 and 25 are cancelled. Claims 1-5, 7-24 and 26-42 are pending. Claims 1-5, 7-21, 24 and 26-42 are examined.

Claim Rejections - 35 USC § 112

Claims 1-5, 7-21 and 24 remain and new Claims 26-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant asserts that hybridizations conditions are taught beginning on page 13 line 34 of the specification (response page 7, 4th paragraph) and that a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the stringent hybridization conditions set forth in the claim yield structurally similar polynucleotides (response page 7, 5th paragraph). The hybridizations conditions recited by Applicant are described as stringent which is a relative term. Further, the conditions recited on page 14, such as temperature, salt concentration, and duration are unspecified. 2X SSC is not recognized by one of skill in the art as a salt concentration for a highly stringent hybridization. Applicant does not indicate specifically at which temperature the hybridization should be conducted and for how long. Applicant has not adequately described the representative genus of polynucleotides having 85% sequence identity to or that hybridize under unspecified hybridization conditions to a potato beta amylase gene.

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Claims 1-5, 7-21 and 24 remain and new Claims 26-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a cDNA fragment comprising SEQ ID NO: 1 or encoding potato beta amylase of SEQ ID NO: 2; transformation and regeneration of a potato plant comprising said cDNA fragment; and modified starch in transgenic potato transformed with said cDNA fragment does not reasonably provide enablement for any other DNA sequences other than SEQ ID NO: 1 or those that encode SEQ ID NO: 2, or for modifying starch in any other plant other than potato. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant asserts that there would be no undue burden to isolate a sequence having at least 85% sequence identity to SEQ ID NO: 1 and still encode a polypeptide that has the function of a potato beta amylase (response page 8). Applicant has not taught which nucleic acid residues when changed would still retain the function of a potato beta amylase or which substitutions should be avoided, and as such one of skill in the art would be required to practice trial and error experimentation to discover a functional embodiment given the lack of teaching in the specification and in the art.

Applicant asserts that newly added claims 27-42 relate to the use of fragments of SEQ ID NO: 2 for antisense suppression and sense co-suppression of endogenous gene expression and that the construction and testing of oligonucleotides is well within the skill of one of skill in the art (response page 8, 3rd paragraph). Applicant should realize that although one of skill in the art can make and test oligonucleotides for their ability to suppress starch production in a plant the specification has not provided any guidance for making and using any particular fragment of

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SEQ ID NO: 1 and thus one of skill in the art would be required to practice undue trial and error with a multitude of non-exemplified oligonucleotides in a myriad of non-exemplified transformed plant species. Further, Applicant has not addressed the unpredictability of altering starch biosynthesis as taught in the references of Kossmann and Willmitzer.

Claims 1-5, 7-21 and 24 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. All dependent claims are included in the rejection.

At Claim 1, line 10, "under stringent conditions" is indefinite. Stringency is a relative term that encompasses low, moderate, and high stringency. Recitation of the high stringency conditions; i.e. salt concentration (e.g. 0.1X SSC), temperature, and duration of the hybridization within the claim would obviate this rejection.

At Claim 2, line 10, "under stringent conditions" is indefinite. Stringency is a relative term that encompasses low, moderate, and high stringency. Recitation of the high stringency conditions; i.e. salt concentration (e.g. 0.1X SSC), temperature, and length of duration of the hybridization within the claim would obviate this rejection.

At Claim 2, the Markush group recited in section (b) is improper for including nucleic acid molecules when the group is drawn to proteins selected from Group A. Before "glucosidases" insert --and--, following "glucosidase" insert --;--, following that, the section beginning with "nucleic acid molecules" should have its own section, i.e. (c).

Claims 12-13 and 24 are indefinite for depending upon newly cancelled Claim 6.

Claim 24 provides for the use of nucleic acid molecules or plant cells, respectively, but, since the claim does not set forth any steps involved in the method/process, it is unclear what

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method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 24 remains rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

Claims 1-5, 7-12 and 24 remain and new Claims 26-27, 30-34, and 37-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshida N. *et al.*, Journal of Biochemistry, 1991, Vol. 110, pp. 196-201.

Applicant asserts that the attached alignment teaches only 54.9% sequence identity that is outside the scope of the present claims (response page 10). The hybridization conditions in part c) of Claim 1 are indefinite as argued supra. Since the claim recites a Markush group, it can be interpreted to exclude part b).

Yoshida teaches the cloning, sequencing, and expression in *E. coli* of sweet potato beta-amylase (Abstract). The recitation of conditions of unspecified stringency in the claims are permissive of non-specific binding and thus the limitation of Claims 1-5, 7-12, 24 and 26 read upon the sweet potato beta amylase. Further, Claims 27, 30-34, and 37-41 recite a fragment of SEQ ID NO: 2 of unspecified length encoded by a nucleic acid fragment of at least 15 nucleotides, which is taught by Yoshida as made clear by Applicant's alignment at nucleotide positions 934 to 949.

Thus the reference teaches all the limitations of Claims 1-5, 7-12, 24, 26-27, 30-34, and 37-41.

Claims 27, 30-34, and 37-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Sadowski J. et al., GenBank Accession Number JQ2248 first published in Plant Physiology 1993, Vol. 102; pp. 315-316.

Sadowski teaches a beta amylase from rye comprising an amino acid fragment from residues 88 to 99 which are the same as amino acid residues 188-199 of the potato beta-amylase of SEQ ID NO: 2 wherein the nucleic acid fragment encoding said rye amino acid fragment is at least 15 nucleotides in length, wherein a cloning vector is inherently taught, and wherein sense and antisense orientation and inhibition of endogenous gene expression by either antisense or sense co-suppression are also inherent properties of the nucleic acid fragment. Further, Claim 34(b) recites a fragment of unspecified length and identity that when introduced into a plant inhibits synthesis of the endogenous protein which also reads upon the sequence taught by Sadowski and is thus taught inherently by the stated reference.

Thus the reference teaches all the limitations of Claims 27, 30-34, and 37-41.

Claim Rejections - 35 USC § 103

Claims 1-5, 7-21 and 24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor M. *et al.*, WO 97/24448 published July 10, 1997 in view of Yoshida N. *et al.*, Journal of Biochemistry, 1991, Vol. 110, pp. 196-201.

Applicant asserts that the teachings of Yoshida are distinct from those of the instant invention with respect to sequence identity (response page 10). The claims are indefinite and broad as discussed supra, and are not limited to a particular sequence identity.

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Applicant asserts that Yoshida teaches beta-amylase proteins are likely to be storage proteins and that the reference teaches away from the present invention (response page 10). Applicant's attention is directed to the abstract of the Yoshida reference where it is clearly stated that soluble extracts of E.coli harboring the cDNA of the sweet potato beta amylase protein demonstrated amylolytic activity that migrated to the same position in a gel as that of the beta amylase purified from sweet potato establishing the protein as an enzyme. Further, Applicant's pagination for the Yoshida reference does not reflect the page numbering of the cited reference.

Claims 28-29 and 35-36 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest nucleic acid fragments of at least 150 nucleotides and 500 nucleotides encoding a fragment of SEQ ID NO: 2.

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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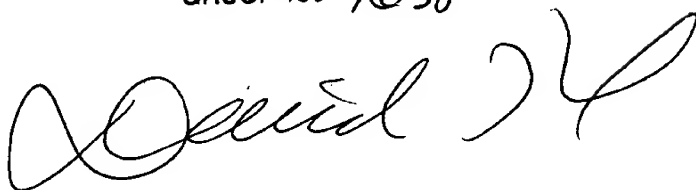
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.

Russell Kallis Ph.D.
August 28, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

A handwritten signature in cursive script, appearing to read "David T. Fox", followed by a large, stylized flourish or mark.